

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 07 NOV 2003

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Applicant's or agent's file reference 96700/791	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/01149	International filing date (day/month/year) 15 January 2003 (15.01.2003)	Priority date (day/month/year) 17 January 2002 (17.01.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 5/10, 5/12, 15/63, 15/85; C12P 21/02; C12Q 1/02, 1/68 and US Cl.: 435/6, 29, 69.1, 320.1, 325, 326, 455		
Applicant ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 18 August 2003 (18.08.2003)	Date of completion of this report 19 October 2003 (19.10.2003)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Corthea Lawrence For</i> Terry A. McKelvey Telephone No. 703-308-0196	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/01149

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-43 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 44-65, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the drawings:
pages 1-7, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 5-33, 39-57, 63-96, 101-124, 128-158, 161-179, 186-202, 208-213, 222-261

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-33, 39-57, 63-96, 101-124, 128-158, 161-179, 186-202, 208-213 and 222-261 are so unclear that no meaningful opinion could be formed (*specify*):

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.
☒ no international search report has been established for said claims Nos. 5-33, 39-57, 63-96, 101-124, 128-158, 161-179, 186-202, 208-213, 222-261

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-4, 34-38, 58-62, 97-100, 125-127, 159-160, 180-185, 203-207, and 214-221 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest inducing a mutation of a gene within 2 kb of a promoter comprising expressing a transgenic activation-induced cytidine deaminase (AID) gene, method of inducing a class switch or altering an affinity in an antibody chain comprising expressing an AID gene, a eukaryotic cell comprising a transgenic AID gene under inducible expression, a non-B-cell eukaryotic cell expressing an AID gene, and a hybridoma expressing an AID gene.

Claims 1-4, 34-38, 58-62, 97-100, 125-127, 159-160, 180-185, 203-207, and 214-221 the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 1-4, 34-38, 58-62, 97-100, 125-127, 159-160, 180-185, 203-207, 214-221

The opinion as to Novelty was negative (No) with respect to claims NONE

The opinion as to Inventive Step was positive (Yes) with respect to claims 1-4, 34-38, 58-62, 97-100, 125-127, 159-160, 180-185, 203-207, 214-221

The opinion as to Inventive Step was negative (NO) with respect to claims NONE

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-4, 34-38, 58-62, 97-100, 125-127, 159-160, 180-185, 203-207, 214-221

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

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NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US03/01149	Applicant's or agent's file reference 96700/791	Date of informal communication (day/month/year) 10 October 2003 (10.10.2003)
Applicant ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY		

<u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal	<u>Participants</u> <input type="checkbox"/> Applicant: AL/BER,T EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNI <input checked="" type="checkbox"/> Agent: Craig Arnold <input checked="" type="checkbox"/> Examiner(s): Terry McKelvey	<input type="checkbox"/> Identity checked <input checked="" type="checkbox"/> authorization checked <input type="checkbox"/> personally known
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Summary of communication:

The applicant agreed to receive the instant International Preliminary Examination Report in lieu of a Written Opinion

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☐ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US
Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No.

Authorized officer

Terry A. McKelvey

Telephone No. 703-308-0196

Form PCT/IPEA/428 (July 1992)